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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,803	10/10/2003	Roberto Crea	CREA-02	2158

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EXAMINER	
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ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.**	**Applicant(s)**	
	10/683,803	CREA, ROBERTO	
	Examiner	**Art Unit**	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007 & 07 December 2007*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13 and 15-17* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-11,13 and 15-17* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11, 13 and 15-17 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed August 22, 2007 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Applicant's supplemental amendment filed December 7, 2007 correcting the deficiencies noted in the notice of non-compliance dated November 26, 2007 has also been received and entered into the present application.

Claims 1-11, 13 and 15-17 are pending and under examination. Claims 1, 13 and 15-16 are amended.

Applicant's arguments, filed August 22, 2007 and December 7, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Present Claims 1-11

Present claim 1 is directed to a composition comprising acetyl-L-carnitine or a pharmaceutically acceptable salt thereof and a mixture of olive vegetation water hydroxytyrosol-containing polyphenols.

In particular, the specification and claims as originally filed fail to provide adequate written description for the use of a "mixture of olive vegetation water hydroxytyrosol-containing polyphenols" (claim 1).

Applicant relies upon the instant specification at paragraph [0022] to support the newly amended limitation directed to a “mixture of olive vegetation water hydroxytyrosol-containing polyphenols” (claim 1), which states, “There is a proprietary two-step process to utilize olive water rich in harvesting antioxidant polyphenols. First, the pits are removed from the olives. Next the pitted olives are pressed, which removes both water and oil from the olives. Then the polyphenolic-rich water is separated from the oil and processed to avoid air oxidation and to release the highest quantity of antioxidant activity. Olive water from the olive oil milling process, or vegetation water, thus becomes an economical and yet previously unused source of natural antioxidant polyphenols (including hydroxytyrosol). Two patents, U.S. Pat. No. 6,165,475 and 6,197,308, both to Roberto Crea, describe this process in detail and are hereby incorporated by reference. Oleuropein also is commercially obtained from olive leaves and can be added to the aqueous extract of olives.”

However, such disclosure of the use of olive vegetation water that contains antioxidant polyphenols, including hydroxytyrosol, fails to provide adequate written support to now narrow the claims to read upon the use of “hydroxytyrosol-containing polyphenols”. Specifically, the instant specification (see, e.g., para.[0022]) and claims as originally filed support the use of olive vegetation water that contains antioxidant polyphenols (one of which may be hydroxytyrosol), but fails to provide written support for the use of a mixture of olive vegetation water hydroxytyrosol-containing polyphenols. This is because the disclosure of olive vegetation water containing polyphenols, one of which is hydroxytyrosol, does not support the narrowing limitation to now require that all of the polyphenols contain, in some way, hydroxytyrosol (i.e., by virtue of the recitation of "hydroxytyrosol-containing polyphenols"). In other words, the limitation "hydroxytyrosol-containing" polyphenols indicates that each of the polyphenols contained within the mixture contains, in some form, hydroxytyrosol, whereas the specification and claims as originally filed only provide support for a mixture of polyphenols, wherein one of the polyphenols is hydroxytyrosol. It is clear, therefore, that newly amended claim 1 represents a narrowing of the subject matter both originally disclosed and originally claimed that was clearly not within Applicant's possession at the time of the invention.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the use of a "mixture of olive vegetation water hydroxytyrosol-containing polyphenols" (claim 1).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Present Claims 16-17

Present claim 16 is directed to a method of ameliorating the effects of tissue damage due to free radicals generated by environmental pollution, of preventing brain or myocardial lesions induced by free radicals following cerebral or myocardial ischemia and attendant reperfusion, of preventing diabetic or toxic neuropathies or metabolic disorders of glucose utilization, said method comprising administering to a subject a composition comprising acetyl-L-carnitine or a pharmacologically acceptable salt thereof and a carnitine selected from the group consisting of L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine or their pharmacologically acceptable salts or mixtures thereof and a mixture of olive vegetation water polyphenols containing hydroxytyrosol.

In particular, the specification and claims as originally filed fail to provide adequate written description for "ameliorating the effects of tissue damage due to free radicals generated by environmental pollution" (claim 16).

Applicant relies upon the instant specification at paragraphs [0015-0016] to support the newly added method for ameliorating the effects of tissue damage due to free radicals generated by environmental pollution. Paragraph [0015] provides written support for the prevention of tissue damage due to free radicals generated by environmental pollution by administering the claimed composition and paragraph [0016] provides for the treatment of the same by administering the claimed composition.

However, such disclosure of the treatment or prevention of tissue damage due to the presence of free radicals due to environmental pollution fails to provide adequate written support to now narrow the claims to read upon the amelioration of the effects of tissue damage by administering the same. Specifically, though "amelioration" may be interpreted to fall within the scope of “treating” as recited in the instant specification at paragraph [0016], the term “treating” *per se* fails to designate the particular effect that the claimed composition has upon the claimed disorder, whereas the newly added term “ameliorating” circumscribes a particular effect that the claimed composition has upon the claimed disorder. This is a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of ameliorating the effects of tissue damage due to free radicals generated by environmental pollution using the claimed carnitine-polyphenol composition. Rather, Applicant was solely in possession of the concepts of using the claimed composition for (1) the treatment of tissue damage due to free radicals generated by environmental pollution or (2) the prevention of tissue damage due to free radicals generated by environmental pollution.

As stated in MPEP §2163, “The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement.” However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of “ameliorating the effects of tissue damage due to free radicals generated by environmental pollution" (claim 16).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Present claim 13 is directed to a method of treating a disease caused by free radicals due to environmental pollution, brain or myocardial lesions induced by free radicals following cerebral or myocardial ischemia and attendant reperfusion, atherosclerotic lesions and tissue proliferative processes, diabetic or toxic neuropathies, and metabolic disorders of glucose utilization, said method comprising administering to a subject a composition comprising acetyl-L-carnitine or a pharmacologically acceptable salt thereof and optionally a carnitine selected from the group consisting of L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine, or their pharmacologically acceptable salts or mixtures thereof and a mixture of olive vegetation water polyphenols containing hydroxytyrosol.

Present claim 16 is directed to substantially similar subject matter, but for the fact that method is directed to ameliorating the effects of tissue damage due to free radicals, etc.

In particular, the specification as originally filed fails to provide adequate written description for the genus of metabolic disorders of glucose utilization (claims 13 or 16) or toxic neuropathies (claims 13 or 16).

MPEP §2163 states, "The issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not convention in the art or known to one of ordinary skill in the art…The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))…Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Applicant states at p.5, para.[0016], of the specification, "Another embodiment is a method of treating a disease brought about by the presence of free radicals due to environmental pollution, brain or myocardial lesions induced by free radicals following cerebral or myocardial ischemia and attendant reperfusion, atherosclerosis lesions and tissue proliferative processes, diabetic or toxic neuropathies, and of metabolic disorders in glucose utilization."

Applicant has failed to provide at least any exemplary "metabolic disorders of glucose utilization" or exemplary "toxic neuropathies", let alone any limiting definition of the genus of metabolic disorders of glucose utilization or the genus of toxic neuropathies, that Applicant was in possession of, and intended to be treated using the presently claimed antioxidant composition, at the time of the invention. In other words, Applicant has failed to define each respective genus of disorders in such a manner as to provide adequate written description of the full scope of the claimed genera by providing, for example, at least a reasonably representative set of species to circumscribe the genus of metabolic disorders of glucose utilization and/or toxic neuropathies. Further, Applicant has failed to provide guidance as to how one of ordinary skill in the art would go about identifying metabolic disorders of glucose utilization and/or toxic neuropathies, and, thus, would have been amenable to treatment with the presently claimed composition, without having to execute hit or miss testing practices in a variety of different disorders to determine if such disorders were amenable to the claimed combination therapy.

The fact that the instant specification fails to clearly delineate the metes and bounds of the claimed genus of metabolic disorders of glucose utilization and/or toxic neuropathies and, further, fails to provide a reasonably representative set of species of such disorders to show that Applicant was actually in possession of the full scope of the claimed genera, is clearly indicative that the instant specification lacks adequate written description for the claimed genus of (1) metabolic disorders of glucose utilization or (2) toxic neuropathies. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention." Please reference MPEP §2163.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the genus of metabolic disorders of glucose utilization (claims 13 or 16) or toxic neuropathies (claims 13 or 16).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of tissue damage due to free radicals generated by environmental pollution, brain or myocardial lesions induced by free radicals following cerebral or myocardial ischemia and attendant reperfusion, diabetic or toxic neuropathies or metabolic disorders of glucose utilization using the claimed combination therapy, does not reasonably provide enablement for the prevention of brain or myocardial lesions induced by free radicals following cerebral or myocardial ischemia and attendant reperfusion, diabetic or toxic neuropathies or metabolic disorders of glucose utilization using the claimed combination therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

For the purposes of consideration under 35 U.S.C. 112, first paragraph, the instant rejection focuses on the particular condition of metabolic syndrome, which is considered to be a "metabolic disorder of glucose utilization" as provided for in claim 16. However, the reasons stated here concerning the burden of enabling the prevention of the condition of metabolic syndrome apply also to myriad of other conditions encompassed by the present claims, but for the obvious difference in the type of disorder.

The presently claimed invention is directed to a method of ameliorating the effects of tissue damage due to free radicals generated by environmental pollution, of preventing brain or myocardial lesions induced by free radicals following cerebral or myocardial ischemia and attendant reperfusion, of preventing diabetic or toxic neuropathies or metabolic disorders of glucose utilization, said method comprising administering to a subject a composition comprising (a) acetyl-L-carnitine or a pharmacologically acceptable salt thereof and a carnitine selected from the group consisting of L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine or their pharmaceutically acceptable salts or mixtures thereof and (b) a mixture of olive vegetation water polyphenols containing hydroxytyrosol. Present claim 17 provides for a weight ratio of (a):(b) from 100:1 to 1:10.

As set forth in *In re Marzocchi et al.,* 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains the teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112, *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support*; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added)

In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would not accept on its face that the prevention of metabolic syndrome, by administering a pharmaceutical composition of acetyl-L-carnitine in combination with another carnitine (i.e., L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine or their pharmaceutically acceptable salts or mixtures thereof) and a mixture of olive vegetation water polyphenols containing hydroxytyrosol, could actually be achieved. Based upon the state of the art, as discussed below, the artisan would have only accepted that the treatment of such a condition could be achieved with this specific combination of agents.

The present claims circumscribe a method for preventing metabolic disorders of glucose utilization (e.g., metabolic syndrome) by administering a pharmaceutical composition of acetyl-L-carnitine in combination with another carnitine (i.e., L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine or their pharmaceutically acceptable salts or mixtures thereof) and a mixture of olive vegetation water polyphenols containing hydroxytyrosol. That is, in order to be enabled to practice the present invention, the skilled artisan would have to accept that by administering this combination of acetyl-L-carnitine in combination with another carnitine (i.e., L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine or their pharmaceutically acceptable salts or mixtures thereof) and a mixture of olive vegetation water polyphenols containing hydroxytyrosol, patients would be protected against developing such a disorder. In other words, the skilled artisan would have understood the term "prevention", in its broadest reasonable interpretation consistent with MPEP §2111, to mean that the incidence of developing such a condition would be essentially 0% and could be reasonably expected not to occur. Because such absolute success is not reasonably possible with most diseases or disorders, especially a condition as complex and poorly understood as metabolic syndrome, the specification, which lacks any direction or guidance as to how prevention of metabolic syndrome could actually be achieved, is viewed as lacking an enabling disclosure of the entire scope of the claimed invention.

Regarding the prevention of metabolic syndrome, the objective truth that such a condition may be prevented is doubted because the art expressly recognizes the complex nature and poor understanding of this syndrome and the predisposing factors that characterize this condition.

In this regard, Grundy ("Metabolic Complications of Obesity", Endocrine, 2000) is cited. Applicant's attention is drawn particularly to the abstract, which states, "The rising prevalence of obesity is accompanied by an increasing number of patients with the metabolic complications of obesity. The major complications come under the heading of the metabolic syndrome. This syndrome is characterized by plasma lipid disorders (atherogenic dyslipidemia), raised blood pressure, elevated plasma glucose, and a prothrombotic state. The clinical consequences of the metabolic syndrome are coronary heart disease and stroke, type 2 diabetes and its complications, fatty liver, cholesterol gallstones, and possible some forms of cancer. At the heart of the metabolic syndrome is insulin resistance…Obesity is the predominant factor leading to insulin resistance, although other factors play a role. The mechanistic link between insulin resistance and the metabolic syndrome is complex. The relationship is modulated by yet other factors, such as physical activity, body fat distribution, hormones, and a person's genetic polymorphic architecture. A better understanding of the molecular basis of this relationship is needed…In addition, understanding at the clinical level will lead to improved management of these complications."

Given that the art expressly acknowledges that the condition of metabolic syndrome and insulin resistance (the primary condition that characterizes metabolic syndrome and results in impaired glucose utilization) as being complex, the skilled artisan would have recognized that the state of the art with regard to metabolic syndrome is not well defined, and is, therefore, unpredictable, such that one of ordinary skill in the art would not accept on its face Applicant's statement that metabolic syndrome could be prevented because the pathophysiology of such a condition is not particularly well characterized. In light of such, the artisan would have required sufficient direction as to how the administration of the presently claimed combination of active agents could actually prevent the development of metabolic syndrome and the patient population in need of prevention could have been readily identified without requiring an undue level of experimentation such that the artisan would have been imbued with at least a reasonable expectation of success. Such success would not have been reasonably expected give that absolute prevention is an outcome not reasonably expected by one of ordinary skill in the art and, further, Applicant has failed to provide any guidance as to how such a population of patients would be identified such that the presently claimed combination of agents could actually be used for achieving the objective of prevention. Absent this disclosure, the present specification fails to enable the full scope of this invention as it relates to the objective of prevention and, thus, fails to rebut the presumption of unpredictability in the art with regard to this same objective.

Furthermore, given the breadth of conditions characterizing metabolic syndrome (i.e., plasma lipid disorders (atherogenic dyslipidemia), raised blood pressure, elevated plasma glucose, and a prothrombotic state), prevention or prophylaxis against metabolic syndrome would necessarily involve preventing each one or more of the conditions known to be associated with such a syndrome. Such a situation would require the skilled artisan to determine whether the active agents of the present claims are effective in preventing any one or more of these conditions and such a process would amount to undue experimentation, given the breadth and disparate nature of each of these conditions and the poor clinical understanding of metabolic syndrome in general.

Moreover, despite the fact that the art recognizes particular pathophysiological manifestations that contribute to the development of metabolic syndrome (see Grundy, citation *supra*), the fact that a patient may exhibit any one or more of such symptomatic complications does not necessarily mean that the patient is predisposed to developing metabolic syndrome. It is the occurrence and interaction of multiple physiological symptoms, as well as other physiologic factors, such as obesity, genetic conditions and/or predispositions, body fat distribution, etc., that contribute to the development of the condition. Accordingly, the circumstances of each individual patient must be carefully considered when determining patients in need of metabolic syndrome prevention. In other words, the variability among patients precludes a common, art-accepted protocol for metabolic syndrome prevention in all patients, given that each patient has risk factors or circumstances unique to that individual, which must be taken into consideration when determining the most effective approach to prevention of metabolic syndrome.

It is in this regard that Applicant is directed to the MPEP at §2164.08. All questions of enablement are evaluated against the claimed subject matter. Concerning the breadth of a claim relevant to enablement, the only relevant concern is whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of enablement involves the determination of how broad the claim is with respect to the disclosure and the determination of whether one skilled in the art is enabled to use the *entire scope* of the claimed invention without undue experimentation.

Applicant's instant specification conspicuously lacks any disclosure or teaching of manner and process of using the presently claimed combination of acetyl-L-carnitine optionally in combination with another carnitine (i.e., L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine or their pharmaceutically acceptable salts or mixtures thereof) and a mixture of olive vegetation water polyphenols containing hydroxytyrosol for achieving the objective of prevention of metabolic syndrome. Nowhere does the specification disclose how those patients in need of prevention of metabolic syndrome could be identified, what criteria would be used to determine such patients and how they would be treated using the presently claimed combination of agents such that the skilled artisan would have been imbued with at least a reasonable expectation of success in determining such patients without the burden of an undue level of experimentation. Due to the unpredictable nature of the pathophysiological manifestations of metabolic syndrome and the poor clinical understanding of this condition in the art, as well as the absence of any guidance or direction as to how the skilled artisan would go about identifying patients in need of prevention, the instant disclosure is viewed as lacking enablement for this aspect of the present invention.

In light of these reasons, it is clear that the present specification fails to provide adequate guidance as to how one skilled in the art would accomplish the objective of preventing metabolic syndrome, given what is disclosed in the present specification. Given the highly unpredictable state of the art and, furthermore, given that Applicant has failed to provide adequate guidance or direction as to how to practice the full scope of the presently claimed invention without undue experimentation, the specification lacks any basis for claiming the prevention of metabolic syndrome without obligating the skilled artisan to perform an undue level of experimentation in order to determine how such an aspect of the invention would actually be practiced. While the lack of a working embodiment cannot be the sole factor in determining enablement, the absence of substantial evidence commensurate in scope with the presently claimed subject matter, in light of the unpredictable nature of the art and the direction (or lack thereof) that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole.

The basis for the present rejection is not simply that experimentation would be required, since it is clear from the state of the prior art and Applicant's disclosure and remarks that experimentation in this particular art is not at all uncommon, but that the experimentation required in order to practice this aspect of the invention would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, “The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*.” (emphasis added)

In view of the discussion of each of the preceding seven factors, the level of skill in the art is high and is at least that of a medical doctor with several years of experience in the art.

As the cited art and discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that prevention of the claimed disorders could be achieved using acetyl-L-carnitine optionally in combination with another carnitine (i.e., L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine or their pharmaceutically acceptable salts or mixtures thereof) and a mixture of olive vegetation water polyphenols containing hydroxytyrosol. In order to actually achieve such a result, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue experimentation in order to practice the full scope of the embodiments of the presently claimed invention.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza (U.S. Patent No. 6,365,622; 2002) or Cavazza (WO 00/11968; 2000), in view of Crea et al. (U.S. Patent No. 6,165,475; 2000), further citing to STN Registry Nos. 10597-60-1 and 34422-12-3 to each show a fact.

The rejection is set forth below as it applies to Cavazza (U.S. Patent No. 6,365,622; 2002). However, the rejection is entirely applicable to Cavazza (WO 00/11968; 2000), but for the differences the citation of page and line numbers.

Cavazza teaches a composition formulated for oral administration as a dietary supplement (claim 7 at col.12, lines 15-16) in solid, semi-solid or liquid form (claim 9 at col.12, lines 20-21) or in the form of tablets, lozenges, pills, capsules, granulates, syrups, injection or drops (claims 10-11 at col.12, lines 22-26), parenteral, rectal or transdermal administration (claim 8 at col.12, lines 17-19) comprising acetyl-L-carnitine or a pharmacologically acceptable salt thereof (claim 1 at col.11, lines 48-51), optionally in combination with at least one other (i.e., meets Applicant's limitation of "mixtures thereof" as recited in present claim 2) carnitine compound selected from L-carnitine or an alkanoyl-L-carnitine, such as propionyl-L-carnitine, valeryl-L-carnitine, isovaleryl-L-carnitine or pharmacologically acceptable salts thereof (claim 2 at col.11, lines 52-56) and further comprising alpha-lipoic acid (claim 1 at col.11, lines 48-51), wherein the weight ratio of acetyl-L-carnitine to alpha-lipoic acid is 100:1 to 1:10 (claim 3 at col.11, lines 57-58) and the composition may further comprise vitamins, coenzymes, mineral substances or antioxidants (claim 6 at col.12, lines 12-14). Cavazza teaches the pharmacologically acceptable salts of the carnitine component may be any one of chloride, bromide, iodide, aspartate, acid aspartate, citrate, acid citrate, tartrate, phosphate, acid phosphate, fumarate, acid fumarate, glycerophosphate, glucose phosphate, lactate, maleate, acid maleate, orotate, oxalate, sulphate, acid sulphate, trichloroacetate, trifluoroacetate or methanesulphate (claims 4-5 at col.11, line 59-col.12, line 2), and that the disclosed composition may be administered for the treatment of diseases brought about by the presence of free radicals due to environmental pollution; brain or myocardial damages induced by free radicals following cereal or myocardial ischemia and attendant reperfusion; toxic or diabetic neuropathies, metabolic disorders of glucose utilization or atherosclerotic lesions and tissue proliferative processes (claims 13-15 at col.12, lines 43-62).

The differences between the Cavazza reference and the presently claimed subject matter lie in that the reference fails to teach the use of a mixture of olive vegetation water polyphenols containing hydroxytyrosol (claims 1, 13 or 16).

Crea et al. (U.S. Patent No. 6,165,475; 2000) discloses stable vegetation water obtained from olives, which contains oleuropein substantially free of monophenolic compounds from olive pits, produced by separating olive pits from olives to obtain a pitless olive pulp, pressing the pitless olive pulp to obtain a liquid-phase mixture including water, oil and olive pulp components, separating the water component from the oil and olive pulp components of the liquid-phase mixture to obtain a water component substantially free of oil and olive pulp, collecting the separated water component and acidifying the water component to a pH between 2-4 to stabilize the component (col.2, l.33-44). Crea et al. further teaches that acidifying the vegetation water enhances storage stability, e.g., extended storage at room temperature for several weeks, and leads to desirable hydrolysis products such as elenolic acid and 2-(3,4-dihydroxyphenyl)ethanol, which have strong antioxidant and antibacterial activity (col.4, l.66-col.5, l.5).

One of ordinary skill in the art would have been motivated to combine the antioxidant composition of Cavazza et al. with the acidified olive vegetation water product of Crea et al., which is enriched with the strong antioxidant compounds elenolic acid (a polyphenol; see chemical structure provided in STN Registry No. 34422-12-3) and 2-(3,4-dihydroxyphenyl)ethanol (synonymous with "hydroxytyrosol", also a polyphenol; see STN Registry No. 10597-60-1), because each was known or recognized in the art to have the same antioxidative function. The very fact that each was known in the prior art to have the same therapeutic utility as an antioxidant raises the reasonable expectation of success that the two compositions, when combined, would have, at minimum, additive, if not synergistic, antioxidant efficacy when combined and, therefore, would have provided enhanced efficacy in treating conditions amenable to a reduction in oxidative stress.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960)."

Response to Applicant's Arguments

Applicant traverses the application of the Cavazza reference(s), stating that it does not provide in any way for the addition, replacement or substitution of lipoic acid. Applicant submits that Cavazza attributes other advantages to lipoic acid which appear to be separate from the antioxidant property, which could contribute to the synergistic effect of lipoic acid with carnitine. Applicant further submits that, to obtain a similar effect with carnitines, one of ordinary skill in the art would search for not just any antioxidant, but one that regulates glucose utilization.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

In response thereto, it is not necessary for Cavazza to expressly provide a teaching of the replacement or substitution of lipoic acid in the disclosed composition in order to support the determination that the use of a mixture of olive vegetation water polyphenols containing hydroxytyrosol would have been obvious. The fact remains that Cavazza teaches a composition of two antioxidant components for the treatment of diseases and conditions brought about by the presence of free radicals due to environmental pollution etc., which are identical to those diseases or conditions presently claimed. Accordingly, the fact that Crea et al. expressly teaches a water-soluble olive extract enriched with the strong polyphenolic antioxidants elenolic acid and 2-(3,4-dihydroxyphenyl)ethanol (synonymous with hydroxytyrosol, see *supra*) provides express motivation to the skilled artisan to add (or, for that matter, even substitute) the lipoic acid component of the composition of Cavazza with the reasonable expectation of success that such a composition would have, at minimum, retained, if not potentiated, its antioxidative effects. It is irrelevant that Cavazza teaches other advantages to lipoic acid. The shared antioxidative property of the components of Cavazza and the polyphenolic water extract of Crea et al. render the combination obvious for the reasons elucidated *supra*, regardless of what other properties may be attributed to lipoic acid.

For these reasons, and those set forth *supra*, rejection of claims 1-11, 13 and 15-17 remains proper and is **maintained**.

Double Patenting (New Grounds of Rejection)

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-22 of U.S. Patent Application No. 11/846,455 or are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over, alternatively, claim 7 of U.S. Patent No. 6,165,475; claim 2 of U.S. Patent No. 6,197,308; or claims 1-6 of U.S. Patent No. 6,416,308, each in view of Cavazza (U.S. Patent No. 6,365,622; 2002) and Saija et al. ("In Vitro Evaluation of the Antioxidant Activity and Biomembrane Interaction of the Plant Phenols Oleuropein and Hydroxytyrosol", *International Journal of Pharmaceutics*, 1998), each already of record.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending patent application or patents are not considered patentably distinct from each other because the copending claims render the present claims obvious.

The copending and/or patented claims clearly provide for a composition comprising a mixture of olive polyphenols contained in an aqueous olive extract (i.e., equivalent to Applicant's presently claimed olive vegetation water) that contains hydroxytyrosol and, e.g., oleuropein, which each demonstrate antioxidative activity, as evidenced by Saija et al. (abstract).

While the copending and/or patented claims are silent as to the use of acetyl-L-carnitine or another carnitine compound, the combination of the hydroxytyrosol/oleuropein components with acetyl-L-carnitine or salts thereof and optionally any one of L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine or isovaleryl-L-carnitine or salts thereof would have been *prima facie* obvious to the skilled artisan in light of the fact that (1) acetyl-L-carnitine was known to maintain mitochondrial activity, which protects against an increase in circulating oxidants from reduced mitochondrial activity (see Cavazza, col.1, lines 30-35; col.1, lines 56-67) and (2) carnitine compounds (e.g., L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine or isovaleryl-L-carnitine or their pharmacologically acceptable salts) were also capable of restoring normal cellular function, such as producing energy by mitochondrial beta-oxidation of fatty acids and branched-chain amino acids (see Cavazza, col.1, lines 30-35 and col.1, line 59-col.2, line 12) and, therefore, each was known to exert the same "antioxidant" effect as that of hydroxytyrosol and oleuropein of the copending and/or patented claims.

Motivation to administer the carnitine compounds of the present claims with the mixture of olive vegetation water polyphenols flows logically from the shared efficacy demonstrated in the prior art of each as potent antioxidative compounds. The skilled artisan would have reasonably concluded that the antioxidative effect exhibited by such carnitine compounds would have achieved, at minimum, additive, if not synergistic, effects when combined with the antioxidant hydroxytyrosol/oleuropein compounds of the copending and/or patented claims.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960)."

Furthermore, the determination of the optimum weight ratios, formulations, and route of administration would have each been matters well within the purview of the skilled artisan. Such a determination would have been made in accordance with a variety of factors, including, but not limited to, the amount to be administered, patient compliance with the regimen, toxicological considerations, such as adverse effects and tolerance to the regimen, pharmacological considerations, and the age, weight, sex, diet and medical condition of the patient.

Accordingly, rejection of claims 1-11 of the present application is deemed proper over claims 17-22 of U.S. Patent Application No. 11/846,455; claim 7 of U.S. Patent No. 6,165,475; claim 2 of U.S. Patent No. 6,197,308; or claims 1-6 of U.S. Patent No. 6,416,308, as claiming obvious and unpatentable variants thereof.

Claims 13 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent Application No. 10/564,924, in view of Cavazza (U.S. Patent No. 6,365,622; 2002) and Saija et al. ("In Vitro Evaluation of the Antioxidant Activity and Biomembrane Interaction of the Plant Phenols Oleuropein and Hydroxytyrosol", *International Journal of Pharmaceutics*, 1998), each already of record.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending patent application or patents are not considered patentably distinct from each other because the copending claims render the present claims obvious.

The copending claims clearly provide for a method of treating early diabetic neuropathy comprising the administration of an aqueous extract of olives, comprising hydroxytyrosol and oleuropein, which each demonstrate antioxidative activity, as evidenced by Saija et al. (abstract).

While the copending and/or patented claims are silent as to the use of acetyl-L-carnitine or another carnitine compound, the combination of the hydroxytyrosol/oleuropein components with acetyl-

L-carnitine or salts thereof and optionally any one of L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine or isovaleryl-L-carnitine or salts thereof would have been *prima facie* obvious to the skilled artisan in light of the fact that (1) acetyl-L-carnitine was known to maintain mitochondrial activity, which protects against an increase in circulating oxidants from reduced mitochondrial activity (see Cavazza, col.1, lines 30-35; col.1, lines 56-67) and (2) carnitine compounds (e.g., L-carnitine, propionyl-L-carnitine, valeryl-L-carnitine or isovaleryl-L-carnitine or their pharmacologically acceptable salts) were also capable of restoring normal cellular function, such as producing energy by mitochondrial beta-oxidation of fatty acids and branched-chain amino acids (see Cavazza, col.1, lines 30-35 and col.1, line 59-col.2, line 12) and, therefore, each was known to exert the same "antioxidant" effect as that of hydroxytyrosol and oleuropein of the copending and/or patented claims. In addition, Cavazza further teaches that the disclosed carnitine compounds are effective for treating diabetic neuropathy (claims 13-15 at col.12, l.43-62).

Motivation to administer the carnitine compounds of the present claims with the mixture of olive vegetation water polyphenols flows logically from the shared efficacy demonstrated in the prior art of each as potent antioxidative compounds, as well as effective treatments for diabetic neuropathy. The skilled artisan would have reasonably concluded that the antioxidative effect and efficacy in treating diabetic neuropathy exhibited by such carnitine compounds would have achieved, at minimum, additive, if not synergistic, effects when combined with the antioxidant and diabetic neuropathy-treating hydroxytyrosol/oleuropein compounds of the copending and/or patented claims.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960)."

Furthermore, the determination of the optimum weight ratios, formulations, and route of administration would have each been matters well within the purview of the skilled artisan. Such a determination would have been made in accordance with a variety of factors, including, but not limited to, the amount to be administered, patient compliance with the regimen, toxicological considerations, such as adverse effects and tolerance to the regimen, pharmacological considerations, and the age, weight, sex, diet and medical condition of the patient.

Accordingly, rejection of claims 13 and 15 as being unpatentable over claims 1-4 of U.S. Patent Application No. 10/564,924, as claiming obvious and unpatentable variants thereof.

Conclusion

Rejection of claims 1-11, 13 and 15-17 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

February 21, 2008

/Ardin Marschel/
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